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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,330	01/05/2005	Hiroyuki Hamada	10873.1598USWO	5251

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EXAMINER	
MARTIN, PAUL C	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/520,330	HAMADA ET AL.	
	Examiner	Art Unit	
	Paul C. Martin	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-8 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-8 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 05 January 2005 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-8 are pending in this application.

Claim Rejections - 35 USC § 112

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, Claim 2 states that the peritoneal equilibrium test (PET) *is performed last of all steps* but that the blood test can be performed *immediately before* the PET. These steps cannot occur simultaneously as the claim clearly staes that PET is the last step. It is suggested that Applicant delete everything in Claim 2 after "...performed last of all the steps..." and add a dependent claim which recites, "The method of Claim 1 wherein the blood test..." in order to overcome the rejection.

Claims 7 and 8 recite the limitation "the peritoneal dialysis fluid whose osmotic pressure is relatively higher" in the second line of the claims. There is insufficient antecedent basis for this limitation in the claim.

The term "relatively higher" in claims 7 and 8 is a relative term which renders the claim indefinite. The term "relatively higher" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen *et al.* (U.S. 5,670,057) in view of Milner (6,077,836) and Kelton *et al.* (1978).

Chen *et al.* teaches a method for testing peritoneal function in order to evaluate a condition of a peritoneal dialysis patient by performing a fluid infusion and fluid drain of a predetermined amount of peritoneal dialysis fluid, analyzing the drain fluid in order to asses the amount of peritoneal dialysis fluid that is retained within the abdominal cavity of a patient, and the concentration of monitored solutes (urea, creatinine, and glucose) in the peritoneal dialysis fluid; performing a peritoneal equilibrium test (PET) and performing a blood test during the PET in order to assess a change in condition in the blood. (Column 2, Lines 14-52)

Chen *et al.* does not teach the repeated (at least three times for each fluid) fluid infusion and drain in alternation of peritoneal dialysis fluids having different osmotic pressures.

Chen *et al.* does not teach the monitoring of the solutes: total protein, albumin, sodium and chlorine, or the extrapolation of the albumin concentration based on total protein concentration in the drain fluid.

Chen *et al.* does not teach the step of performing fluid infusion and fluid drain a plurality of times using dialysis fluids having the same osmotic pressure, then the dwell times are different each time.

Chen *et al.* does not teach that the peritoneal dialysis fluid whose osmotic pressure is relatively higher is infused either first or last in the step of repeatedly performing fluid infusion and drain in alternation for peritoneal dialysis fluids having different osmotic pressures.

Milner teaches the repeated infusion and drain (more than 3 times) of two alternate peritoneal dialysis fluids having different osmotic pressures (Column 23, Lines 54-59), the step of performing fluid infusion and fluid drain a plurality of times using dialysis fluids with the same osmotic pressure with the dwell times being different each time (Column 29, Lines 43-49 and Column 30, Lines 20-25) and the step of either infusing first or last (Column 23, Lines 54-59) the peritoneal dialysis fluid with the relatively higher osmotic pressure, and the monitoring of the solutes: urea, creatinine, total protein, albumin, and glucose. (Column 30, Lines 65-67).

Kelton *et al.* teaches a method for testing peritoneal function wherin the monitored solutes are: total protein, albumin, glucose, creatinine, urea, sodium and chlorine. (Pg. 69, Table 1)

It would have been obvious to the person of ordinary skill in the art at the time of the invention to combine the method of Chen *et al.* for evaluating the condition of a peritoneal dialysis patient using a single infusion/drain of a single peritoneal dialysis fluid, PET, and blood test with the method of Milner discussed *supra* and the specific solutes monitored by Kelton *et al.* because the ordinary artisan would have recognized the value of using peritoneal dialysis solutions of differing osmotic pressures based on the changing needs of individual patients, such changes often occurring over the span is just a few hours. The constant monitoring of specific solutes in the drain solution, combined with PET and a blood test all act as status monitoring steps of peritoneal dialysis of the patient and the administration of a plurality of infusion/drain steps for each dialysis fluid of different osmotic pressure, or the same osmotic pressure, wherein the fluid with the relatively higher osmotic pressure can either administered first or last can be tailored by the ordinary artisan to meet the clinical needs of each individual patient. The extrapolation of the albumin concentration of the drain fluid based on the total protein concentration of the drain fluid would have been obvious to the ordinary artisan because albumin is a protein and it is well known in the art that as total protein of

a solution vs. a control solution increases it can be deduced that its constituent proteins concentrations will likewise increase.

The ordinary artisan at the time of invention would have had a reasonable expectation of success in the combining of these methods based on the individual success and practice of the methods when used individually.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one with ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence or evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Martin
Examiner
Art Unit 1655

11/07/05

PATRICIA LEITH
PRIMARY EXAMINER